

Immediate blood detection

HemoPill[®] acute



Wireless capsule with optical sensor for the detection of acute upper GI bleeding

Simply use the non-endoscopic HemoPill[®] acute capsule to detect acute bleeding in the esophagus, stomach and small intestine. After swallowing, the capsule moves naturally through the patient's digestive tract.

Depending on the location of the bleeding, blood is detected within minutes (e.g. ulcer bleeding in the stomach) or hours (e.g. bleeding in the small intestine) by this novel sensor capsule. Its use does not require any preparation of the patient, the findings are easy to interpret and are displayed in real-time on the associated HemoPill Receiver. The system allows easy patient prioritization and helps to facilitate the daily clinical schedule, e.g. in emergency rooms or endoscopy units.

The small capsule has several advantages for patients. In the case of a positive finding, early endoscopy and therapy may be indicated. If the findings are negative, emergency endoscopy may be postponed or even eliminated, saving the patient an unnecessary procedure and the hospital costs.



HEMOPILL[®]
ACUTE



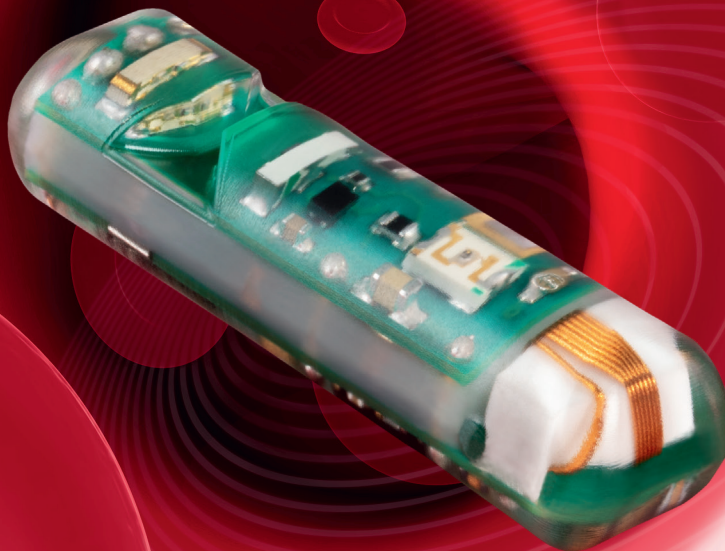
HEMOPILL[®]
RECEIVER

▶ NEW



HemoPill®

Immediate detection of acute bleeding in the oesophagus,
stomach and small intestine



HemoPill® is a new product line for the immediate detection of acute bleeding in the oesophagus, stomach and small intestine. HemoPill® acute is a swallowable sensor capsule that wirelessly sends measured values to a portable receiver (HemoPill® Receiver).

..... HemoPill®

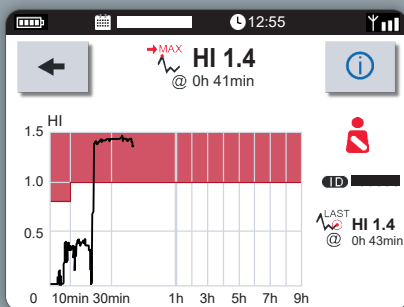
Capsule with innovative sensor technology

- Quick and easy assessment of findings when acute GI bleeding is suspected, e.g. in an emergency or with geriatric patients
- Allows rapid prioritisation of endoscopy procedures on patients in the clinical daily routine or even outside of regular working hours
- Does not require patient preparation and can be used immediately if bleeding is suspected
- Different areas of applications (e.g. endoscopy, emergency room or ICU)
- Integrated microsensor with photometric measuring method for blood detection
- Detection of blood even in small volumes in the lumen
- Safe telemetric data transmission in real time for immediate assessment of findings

..... Application

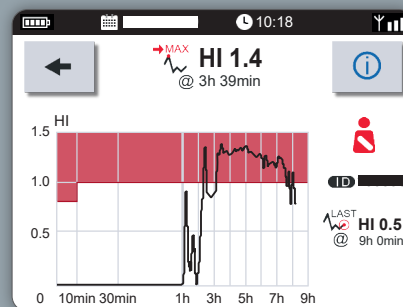
Positive HemoPill® finding

Indication for immediate endoscopy and treatment



Acute bleeding in the stomach

20 minutes after swallowing the HemoPill® acute, a significant increase in the HI value was observed. This indicated acute bleeding in the upper digestive tract. The examination using the HemoPill® was completed after 43 minutes and a gastroscopy was performed immediately. This showed a bleeding angiodysplasia in a gastrojejunal anastomosis, which was successfully treated.

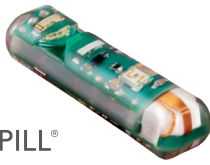


Bleeding in the small intestine

The significant increase in the HI value after 2.5 hours was indication of bleeding in the middle digestive tract. The examination took a total of 9 hours. A subsequent targeted double balloon enteroscopy showed angiodysplasia in the small intestine, which was treated successfully.

Use of the HemoPill® acute in the early clinical phase (July 2019–September 2020).

Source: Prof. Dr. Arthur R. Schmidt & Dr. Armin Kuellmer, Medical Center – University of Freiburg, Germany/Prof. Dr. Juergen Hochberger & Dr. Thomas Brunk, Vivantes Clinic in Friedrichshain, Germany

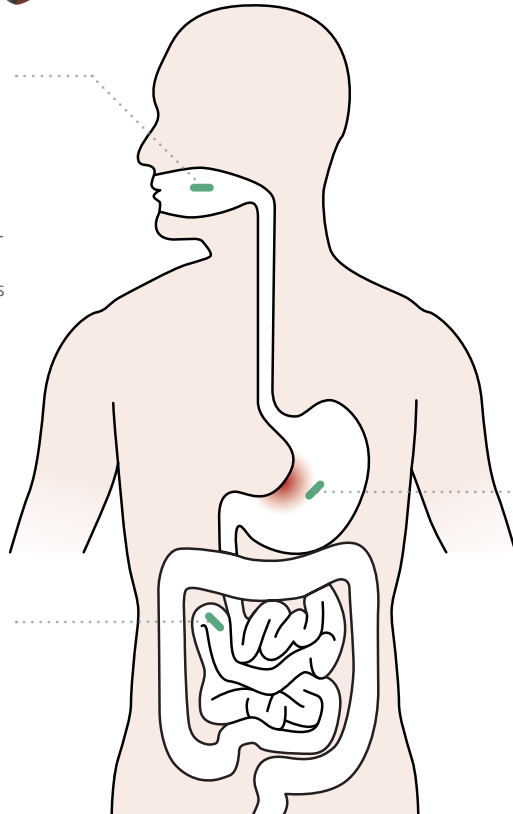


**HEMOPILL®
ACUTE**

After the connection between the HemoPill® acute and HemoPill® Receiver is established, the patient swallows the HemoPill® acute.

After swallowing, the sensor capsule is transported by peristalsis and transmits measured values to the HemoPill® Receiver several times per minute.

The maximum measurement duration is 9 hours. This allows the upper and middle digestive tract to be examined for blood.



**HEMOPILL®
RECEIVER**

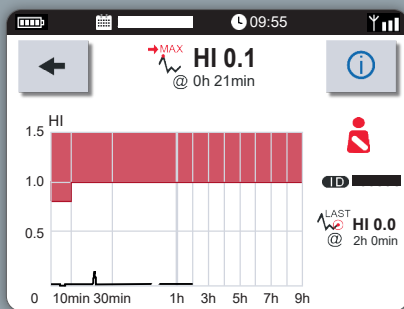


Using the HemoPill® Indicator (HI value), which is shown on the HemoPill® Receiver, acute bleeding is detected immediately during the examination.

A positive result (displayed in the red area of the diagram) means that liquid blood (or haematin) has been detected.

Negative HemoPill® finding

Postponing or avoiding emergency endoscopy

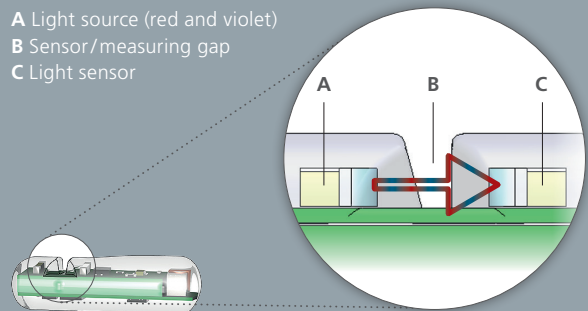


Excluding upper GI bleeding

No increase in the HI value was observed after the capsule was swallowed. Further differential diagnostics identified an aortic dissection as the cause of the anaemia detected in the emergency room. This meant that the patient did not need to undergo an endoscopy.

Sensor principle

- A Light source (red and violet)
- B Sensor/measuring gap
- C Light sensor



The HemoPill® acute capsule has a measuring gap that is supplied alternately with red and violet light. Depending on the medium in the measuring gap (e.g. blood, gastric juice), the light beam is absorbed to varying degrees. If blood is detected, this results in a high HI value, i.e. $HI \geq 0.8$ within 10 minutes or $HI \geq 1.0$ from 10 minutes after swallowing.

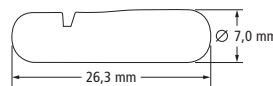
Details and components

The product line consists of a sensor capsule and a portable receiver for immediate detection of acute bleeding in the oesophagus, stomach and small intestine.



Small, swallowable capsule with optical sensor

- Blood detection by direct measurement of blood in the sensor gap, even in an unprepared digestive tract
- Wireless transmission of measured values to the HemoPill® Receiver
- Maximum measuring time: 9 hours
- Length: 26.3 mm; max. diameter: 7.0 mm
- Sterile single-use product



Ref. no. 500.01



Portable receiver for displaying and storing measured values from the HemoPill® acute

- Measured values displayed in real time
- Colour display & touchscreen
- User-friendly handling with integrated battery
- Easy data access with straightforward menu navigation



Ref. no. 500.20

Accessories

HemoPill® Printer

Thermal printer for printing findings

- Connection via USB port
- Print quality maintained for up to 25 years with special thermosensitive paper

The HemoPill® Printer is considered an optional accessory for the HemoPill® Receiver and can be ordered separately.

It is available in the following countries: U.S.A., Canada, Japan and all EU and EFTA member states.

Ref. no. 500.30



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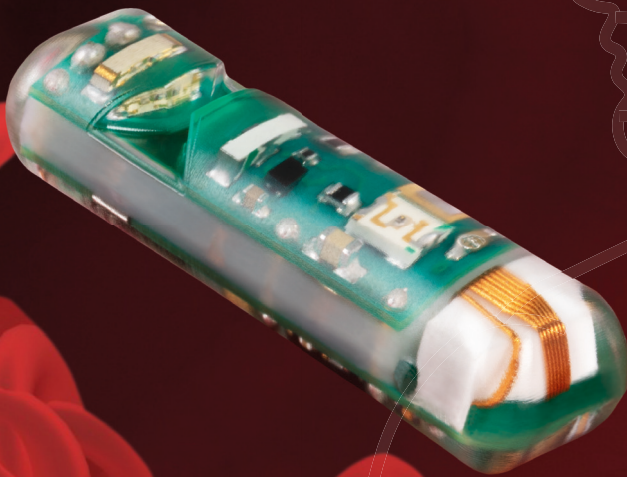
Not for sale in the U.S.A. yet.

Ovesco Endoscopy AG is a medical device company specialising in the fields of telemetric diagnostics, flexible endoscopy and endoluminal surgery. The company develops, manufactures and markets innovative products for the detection and treatment of gastrointestinal disease. Ovesco products are synonymous with efficacy and efficient application.

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Immediate blood detection

HemoPill[®] acute



- Contactless detection of acute bleeding in the oesophagus, stomach and small intestine
- Immediate assessment of findings through realtime data transmission
- Can be used for non-fasting patients
- Simple and safe use

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HEMOPILL[®]
ACUTE



HEMOPILL[®]
RECEIVER

Current clinical data on HemoPill® acute

Pilot study shows feasibility and safety of telemetric testing for acute GI bleeding (DING study)¹

Results:

- Easy swallowing of the capsule, excellent patient acceptance
- No capsule retention (mean time to excretion: 4.33 d, range 1–16 d)
- Successful data transmission in all cases
- True negative detection of all patients without endoscopic bleeding signs (17/17)
- Detection of all bleedings >20ml (2/2)

In n=27 circulatory stable patients with suspected upper gastrointestinal bleeding (GIB), a gastroscopy was performed within 12 h after HemoPill acute ingestion, the amount of bleeding (< 5 ml, 5–20 ml, > 20 ml) was estimated and compared with the results of the HemoPill acute.

HemoPill acute proves to be effective in emergency diagnostics in multicentre data collection²

Results:

- Easy swallowing of the capsule, no capsule retention and no complications (0/61)
- Influence of negative HemoPill findings on the clinical course in 72 % (18/23):
 - » n=10 (40 %) elective endoscopy instead of immediate endoscopy
 - » n=5 (20 %) avoidance of enteroscopy
 - » n=3 (12 %) avoidance of gastroscopy
- True negative detection of all patients without clinical and endoscopic bleeding signs
- Detection of all relevant bleeding

HemoPill acute was used at 12 clinical centres (July 2019 – March 2020) in n=61 circulatory stable patients, primarily with Glasgow-Blatchford Bleeding Score of 10 (range 0 – 19): n=45 (73 %) patients with suspected upper GIB, n=12 (20 %) with suspected middle GIB and n=4 (7 %) patients with successful endoscopic haemostasis and suspected rebleeding.

Application observation points towards HemoPill acute being a new, inexpensive tool for the detection of active bleeding in the small intestine²

Results:

- Complication-free use of the capsule (orally in 9 cases, endoscopic placement in the duodenum in 4 cases)
- Technically successful HemoPill use in all cases
- In all positive cases (7/7), the double balloon enteroscopy performed within 24 h showed angiodysplasias which were successfully treated endoscopically (3/7 with active bleeding during examination)

The HemoPill acute was used in n=13 patients with suspected acute gastrointestinal bleeding and negative gastroscopy: 5 women, 8 men; 28–84 years; Glasgow-Blatchford Bleeding Score: 6–10 (M10, SD2).

1 Schmidt A., Zimmermann M., Bauder M., Kuellmer A., Caca K. [2019]. Novel telemetric sensor capsule for EGD urgency triage: a feasibility study. Endosc Int Open. 7(6):E774-E781. doi: 10.1055/a-0880-5312.

2 Schmidt A., Brunk T. DGE-BV Online Symposium – Diagnostik 2020 – Künstliche Intelligenz und Sensorik [DGE-BV Online Symposium – Diagnostics 2020 – Artificial intelligence and sensor technology], 7 October 2020.

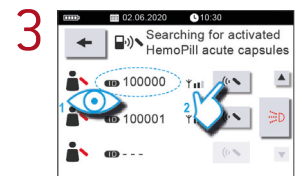
HemoPill application steps



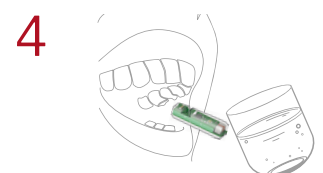
Switch on the HemoPill Receiver



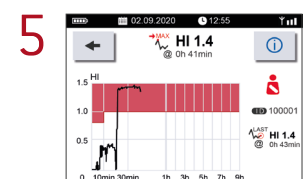
Activate the HemoPill acute in the blister pack



Connect the HemoPill acute to the HemoPill Receiver



Take the HemoPill acute with a glass of water



Evaluate findings: a measured value (HemoPill Indicator, HI) in the red area means that blood has been detected.

HemoPill® acute

Use in patients with COVID-19

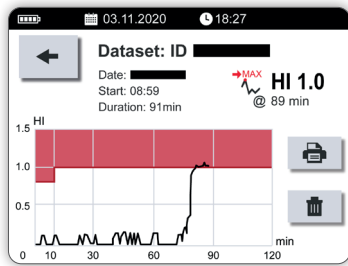


Fig. 1:
Detection of upper GI
bleeding in a COVID-19
patient

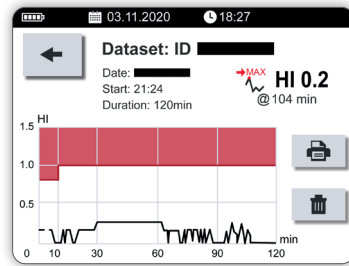


Fig. 2:
Excluding upper GI bleeding
in a patient with suspected
COVID-19

PD Dr. Andreas Wannhoff, Prof. Dr. Karel Caca
RKH Ludwigsburg clinic, Germany, Clinic for Internal Medicine, Gastroenterology,
Haemato-oncology, Pneumology, Diabetology and Infectiology

Query

Endoscopic examinations for patients with COVID-19 pose a potential risk to endoscopy staff. The risk of viral transmission appears to be significantly increased particularly during examinations in the upper gastrointestinal tract. On the other hand, endoscopy is the benchmark in the diagnosis and treatment of gastrointestinal bleeding.

Methodology:

We report our experience with HemoPill acute in patients with suspected gastrointestinal bleeding during the current SARS-CoV2 pandemic.

Results

A HemoPill examination was performed in 2 patients. Patient #1 suffered from COVID-19, cardiac comorbidities as well as severe obesity. During the inpatient stay, the patient reported tarry stools and the haemoglobin levels dropped. The HemoPill examination confirmed the suspected gastrointestinal bleeding: The maximum HI value was 1.0. The subsequent endoscopic diagnosis revealed a stomach ulcer with a non-bleeding vascular stump, which was treated endoscopically and with proton pump inhibitors.

Patient #2 had pronounced anaemia, and gastrointestinal blood loss was suspected. Routine screening for SARS-CoV2 was performed by PCR test. Due to the delay in receiving the test result, a HemoPill investigation was carried out. This remained without evidence of gastrointestinal bleeding (maximum HI value 0.2). Further endoscopic diagnostics could be postponed until the negative test result was received, which at this point in the pandemic was only available after 48 hours.

..... Case Study

HemoPill® acute

Use in patients with COVID-19

Conclusion

The use of HemoPill acute during the COVID-19 pandemic may assist in the indication and scheduling of endoscopic examinations. In patients with a confirmed infection, the need to perform an endoscopy in particular can be confirmed if gastrointestinal bleeding is suspected, thus avoiding unnecessary examinations with a potential risk of transmission. For patients with a pending COVID-19 screening test, HemoPill examination can assist in scheduling the examination, if necessary in an emergency also before receiving the test result or electively afterwards.



O V E S C O

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HemoPill® acute

Assessment of localisation of gastrointestinal bleeding

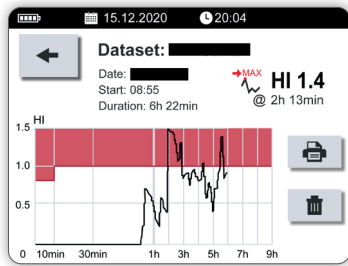


Fig. 1:
Detection of bleeding in
the upper small intestine

PD Dr. Edris Wedi
Sana Offenbach Clinic, Germany, Medical Clinic II / IV
Gastroenterology, Gastrointestinal Oncology and Interventional Endoscopy

Query

An 86-year-old patient with cardiac comorbidity was referred to us for small intestine diagnostics for suspected moderate GI bleeding on ASA therapy. Externally, an oesophago-gastro-duodenoscopy (OGD) and colonoscopy had already been performed without finding a source of bleeding; with a capsule endoscopy, the suspicion of lower small intestinal bleeding was established. When the patient was admitted to our clinic, they had melaena and haemorrhagic anaemia requiring transfusion with an Hb of 7.2 g/dl. In this case we want to evaluate whether the HemoPill acute can be used to assess the localisation of the source of bleeding, and whether the capsule can thus be helpful in selecting the endoscopic procedure.

Methodology

The HemoPill acute is a swallowable capsule with an optical sensor for the immediate detection of acute bleeding in the oesophagus, stomach and small intestine. Fasting or prior purging is not required. The capsule is ingested in an upright position with a glass of water. During the passage through the gastrointestinal tract, the blood sensor takes readings that are sent via radio to a portable receiver that the patient wears in a bag around the abdomen. Blood is detected by the sensor if the HI value exceeds 1.0. The doctor can evaluate the measured values via the receiver while the measured values are being recorded. In the case described, the HemoPill acute was used directly on the day of admission to detect acute bleeding and to determine the further endoscopic procedure. The reading was tracked for 8 hours.

Results

After only 2 hours 13 minutes, the HemoPill acute detected blood (^{MAX}HI 1.4; see Fig. 1), so that, contrary to the external findings, a haemorrhage in the upper small intestine could be assumed. Thus, we initially followed up with an OGD in which an active Forrest Ib haemorrhage was seen in the duodenum from an angiodysplasia and the haemorrhage was successfully stopped by applying 4 clips and APC treatment. Post-intervention, the patient showed no more bleeding signs during the further inpatient stay and the Hb remained stable in serial controls.

..... Case Study

HemoPill® acute



O V E S C O

Assessment of localisation of gastrointestinal bleeding

Conclusion

In our case, the HemoPill acute has proven to be an elegant tool to detect acute bleeding and, in unclear cases, to assess the localisation of the source of bleeding in a timely manner and without patient preparation (no fasting or prior bowel cleansing required) to determine the necessary endoscopic procedure (OGD, oral enteroscopy or anal enteroscopy). By using the HemoPill acute, unnecessary enteroscopy of the lower small intestine could be avoided in our patient. This would have been much more stressful for the patient due to the higher sedation risk of the more time-consuming enteroscopy and the necessary laxative measures.

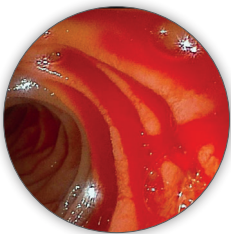


Fig. 2a:
Active Forrest Ib bleeding
in the duodenum

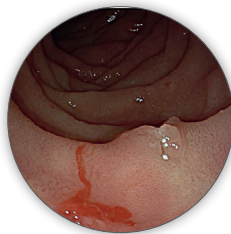


Fig. 2b:
Bleeding angiodysplasia
in the duodenum

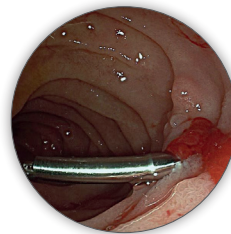


Fig. 2c:
Successful haemostasis
by application of 4 clips
and APC treatment

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